

**TEXAS DEPARTMENT OF HEALTH
PROPOSED RULES FOR BOARD OF HEALTH APPROVAL
COVER MEMORANDUM**

January 2004

Agenda Item No: 10 O

Presenter: Casey S. Blass

**Chief, Bureau of Immunization and
Pharmacy Support**

Summary and Impact:

These are proposed rules concerning the Texas Department of Health (department) immunization registry. The immunization registry is a statewide repository for immunization information on Texas children. The information is available to public health districts, local health departments, physicians, schools, child-care facilities, and parents when record request criteria are met. The proposed rules are necessary to simplify reporting immunization histories to the department and to enhance the effectiveness of the immunization registry under its current authorized legislation. As mandated by House Bill 1921, 78th Legislature, Regular Session (2003), amended Health and Safety Code, §161.007, the proposed rules will help populate the registry by relieving payors and providers of the responsibility for maintaining consent for the registry; will allow parents to submit immunization histories directly to the department; will require healthcare providers to send immunization records directly to the department; will require the department to verify parental consent for each record submitted; and will expand data access to any provider authorized to administer vaccines, payors and state agencies with legal custody of a child.

Government Code, §2001.039, requires that each state agency review and consider for readoption each rule adopted by that agency pursuant to the Government Code, Chapter 2001 (Administrative Procedure Act). The department has reviewed §§100.1-100.11 and has determined that reasons for adopting the sections continue to exist; however, a repeal of the current rules and the proposal of new rules are necessary to simplify the rules and implement House Bill 1921.

The department published a Notice of Intention to Review for §§100.1-100.11 in the Texas Register on May 31, 2002 (27 TexReg 4745).

Description of Stakeholder Participation in Development of Proposed Rules:

The Division solicited input on the proposed rules by e-mail from internal stakeholders including Regional Immunization Program Managers, local health departments, Bureau of Children's Health, and the Women, Infants and Children (WIC) Program. External stakeholder input was solicited from medical organizations, insurance companies, legislators and groups involved with children's health issues. Stakeholders were invited to an informal stakeholder briefing held at the department on November 12, 2003. Stakeholder input was heard at the briefing and written input was accepted through November 14, 2003.

Recommended Board Action:

Approval of proposed rules concerning the Texas Department of Health immunization registry for publication in the *Texas Register* for a 30-day public comment period.

Title 25. Health Services
Part I. Texas Department of Health
Chapter 100 Immunization Registry
Repeal §§100.1-100.11
New §§100.1-100.8

Proposed Preamble

The Texas Department of Health (department) proposes the repeal of §§100.1-100.11 and new §§100.1-100.8, concerning the immunization registry.

The immunization registry is a statewide repository for immunization information on Texas children. The information is available to public health districts, local health departments, physicians, schools, child-care facilities, and parents when record request criteria are met. The proposed rules are necessary to simplify reporting immunization histories to the department and to enhance the effectiveness of the immunization registry under its current authorized legislation. As mandated by House Bill 1921, 78th Legislature, Regular Session (2003), amended Health and Safety Code, §161.007, the proposed rules will help populate the registry by relieving payors and providers of the responsibility for maintaining consent for the registry; will allow parents to submit immunization histories directly to the department; will require healthcare providers to send immunization records directly to the department; will require the department to verify parental consent for each record submitted; and will expand data access to any provider authorized to administer vaccines, payors and state agencies with legal custody of a child.

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Casey S. Blass, Chief, Bureau of Immunization and Pharmacy Support, has determined that for each year of the first five years the sections are in effect there will be no fiscal implications to the state government as a result of enforcing and administering the sections as proposed. Additional immunization histories submitted by providers and parents will be processed using existing resources. There will be no fiscal impact on local government because the immunization registry is a state registry maintained by the department.

Mr. Blass has also determined that for each year of the first five years the sections are in effect the public benefit anticipated through enforcement and administration of the sections as proposed will be to enhance the effectiveness of the registry by providing parents with more complete and accurate immunization histories for their children. The proposed changes will benefit small and micro-businesses like clinics and physicians' offices by reducing confusion regarding parental consent and eliminating the responsibility for providers to maintain evidence of consent. Providers and payors will benefit from expanded access to more complete immunization histories. Providers who currently report immunization records to payors are not required to report those records to the registry. Under House Bill 1921, as reflected in the proposed rules, these providers will be required to report to the registry. There will be no impact on local employment.

Comments on the proposal may be submitted to Janie Garcia, Immunization Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756, (512) 458-7284, extension 6430, or (800) 252-9152. Comments will be accepted for 30 days following publication of this proposal in the Texas Register.

The repeal and new sections are proposed under the authority of Health and Safety Code, §161.007, which gives the Texas Board of Health (board) the right to develop rules to implement the immunization registry; and Health and Safety Code, §12.001, which provides the board with the authority to adopt rules for the performance of every duty imposed by law on the board, the department, and the commissioner of health.

The amendment, repeal, and new sections affect the Health and Safety Code, Chapters 12 and 161. The review of the rules implements Government Code, §2001.039.

Sections for Repeal

- §100.1. Definitions.
- §100.2. Inclusion of Information and Confidentiality.
- §100.3. Providers and Health Plans.
- §100.4. Withdrawal of Consent.
- §100.5. Reportable Information.
- §100.6. Information Included in the Immunization Registry Prior to September 1, 1997.
- §100.7. Data Quality Assurance.
- §100.8. Health Plans Shall Provide Immunization History to the Department.
- §100.9. Reports.
- §100.10. Acceptability As An Immunization Record.
- §100.11. Confidentiality.

Legend: (New Rules)

Regular Print = Proposed new language

§100.1. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Child - The person or individual younger than 18 years of age to whom a vaccine has been administered.

(2) Consent - A statement signed by a parent agreeing that the child's immunization history can be included in the registry and that the child's immunization record may be released from the registry.

(3) Data elements - Consistent with 42 U.S.C. §300aa-25, as amended, data elements are defined as the information a provider who administers a vaccine is required to record in a medical record, including:

(A) the date the vaccine is administered;

(B) the type of vaccine administered, vaccine manufacturer and lot number; and

(C) the name, address, and, if appropriate, the title of the provider administering the vaccine.

(4) Department - The Texas Department of Health.

(5) Immunization history - An accounting of all vaccines that a child has received, or evidence of immunity, and other identifying information.

(6) Immunization record - An immunization record contains the name and date of birth of the person to whom a vaccine was administered; dates of vaccine administration; types of vaccine administered; and name and address of the provider that administered the vaccines; or other evidence of immunity to a vaccine-preventable disease. The report generated from the immunization registry is considered an official immunization record.

(7) Immunization registry - The database or single repository that contains immunization histories, which include necessary personal data for identification. This database is confidential, and access to content is limited to authorized users.

(8) Parent - A parent, managing conservator, or legal guardian.

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(9) Payor - An insurance company, a health maintenance organization, or another organization that pays a health care provider to provide health care benefits, including the administration of vaccines to a person younger than 18 years of age.

(10) Provider - Any physician, health care professional, or facility personnel duly licensed or authorized to administer vaccines.

(11) User - An entity or individual authorized by the department to access immunization registry data.

(12) Vaccine - Includes toxoids and other immunologic agents which are administered to children to elicit an immune response and thus protect against infectious diseases.

§100.2. Confidentiality.

(a) Information that individually identifies a child, and is received by the department for the immunization registry, is confidential and may be used by the department for registry purposes only. Unless specifically authorized by Health and Safety Code, Chapter 161, Subchapter A, the department may not release registry information to any individual or entity without the written consent of the person or, if a minor, the parent.

(b) A written confidentiality statement shall be signed by an authorized representative of the user. Any user of the registry shall protect the confidentiality of all immunization histories, records, and reports. A person required to report information to the department for registry purposes or authorized to receive information from the registry may not disclose individually identifiable information to any individual or entity without the written consent of the person or, if a minor, the parent, or except as provided by the Occupations Code, Chapter 159, or the Insurance Code, Article 28B.04.

(c) Registry information is not subject to discovery, subpoena, or other means of legal compulsion for release to any person or entity, except as provided by Health and Safety Code, Chapter 161, Subchapter A. Registry information is not admissible in any civil, administrative, or criminal proceeding.

§100.3. Informing Parent, Managing Conservator, or Guardian.

(a) A parent shall be informed that the department has established and maintains a single repository of immunization records to be used in aiding, coordinating, and promoting efficient and cost-effective childhood communicable disease prevention and control efforts.

(b) The department shall provide written materials and forms to providers for the purpose of informing a parent about the immunization registry and specific information collected in that registry.

(c) The department and providers may use the registry to provide notices by mail, telephone, personal contact, or other means to a parent regarding his or her child who may be due or overdue for a

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particular type of immunization according to the department's immunization schedule.

(d) The first time the department receives registry data, from a person other than the child's parent, for a child for whom the department has received consent to be included in the registry, the department shall send a written notice to the parent disclosing:

(1) that providers and payors may be sending the child's immunization information to the department;

(2) the information that is included in the registry;

(3) the persons to whom the information may be released;

(4) the purpose of the registry;

(5) the procedure to exclude a child from the registry; and

(6) the procedure to report a violation if a parent discovers a child is included in the registry after exclusion has been requested.

§100.4. Registry Consent and Withdrawal.

(a) A parent may consent to the inclusion of the child's immunization history in the immunization registry by doing one of the following:

(1) indicating consent at birth certificate registration, including by electronic signature;

(2) submitting written notification to the department in a format prescribed by the department or substantially similar and mailed to the Texas Department of Health, Immunization Division, 1100 West 49th Street, Austin, Texas 78756, or by calling the Immunization Division at (800) 252-9152 to request a consent form; or

(3) completing written consent to be submitted to the department by a provider or payor.

(b) Consent is required to be obtained only one time, and is valid until the child becomes 18 years of age, unless the consent is withdrawn in writing.

(c) A parent may withdraw consent for the child to be included in the registry at any time by submitting written notification to the department in a format prescribed by the department or substantially similar and mailed to the Texas Department of Health, Immunization Division, 1100 West 49th Street, Austin, Texas 78756, or by calling the Immunization Division at (800) 252-9152 to request a consent withdrawal form. The department shall remove information from the immunization registry for any person for whom consent has been withdrawn, and the department shall send the parent a written confirmation of the removal of the information. The department may not retain individually identifiable information about any person for whom consent has been withdrawn.

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(d) A parent may request exclusion of the child's immunization history from the immunization registry by doing one of the following:

(1) indicating the request for exclusion at birth certificate registration, including by electronic signature; or

(2) submitting written notification to the department in a format prescribed by the department or substantially similar and mailed to the Texas Department of Health, Immunization Division, 1100 West 49th Street, Austin, Texas 78756, or by calling the Immunization Division at (800) 252-9152 to request an exclusion form. On receipt of a written request to exclude a child's immunization records from the registry, the department shall send the parent a written confirmation of receipt of the request, and shall exclude the child's records from the registry. The department may not retain individually identifiable information about any person for whom an exclusion has been requested.

§100.5. Receipt and Release of Registry Data.

(a) The department may obtain the data constituting an immunization record for a child from a public health district, a local health department, the child's parent, a physician to the child, a payor, or any health care provider licensed or otherwise authorized to administer vaccines.

(b) Effective January 1, 2005, the department shall verify consent before including information received from a person other than the child's parent in the immunization registry. Effective January 1, 2005, the department may not retain individually identifiable information about a person for whom consent cannot be verified.

(c) The department may release the data constituting an immunization record for a child to any entity that is described by subsection (a) of this section to a school or child care facility in which the child is enrolled, or to a state agency having legal custody of the child.

(d) A person, including a provider, a payor, or an employee of the department, that submits in good faith an immunization history or data to or obtains in good faith an immunization history or data from the department in compliance with this section is not liable for any civil damages.

(e) The department may release nonidentifying summary statistics related to the registry that do not individually identify a child.

§100.6. Reporting to the Registry.

(a) Data elements regarding an immunization record provided to the department, whether electronically or by other means, shall be submitted in a format prescribed by the department.

(b) Effective January 1, 2005, a health care provider who administers an immunization to a person younger than 18 years of age shall provide data elements regarding an immunization to the department within 30 days of administration of the vaccine. Effective January 1, 2005, the department

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shall verify consent before including the reported information in the immunization registry, and the department may not retain individually identifiable information about a person for whom consent cannot be verified. For immunizations administered prior to January 1, 2005, providers shall provide an immunization history for persons for whom consent to participate in the registry has been obtained unless the immunization history is submitted to a payor.

(c) Effective January 1, 2005, a payor that receives data elements from a provider who administers an immunization to a person younger than 18 years of age shall provide the data elements to the department within 30 days of receipt of the data elements from a provider. Effective January 1, 2005, the department shall verify consent before including the reported information in the immunization registry, and the department may not retain individually identifiable information about a person for whom consent cannot be verified. For immunizations administered prior to January 1, 2005, payors shall provide an immunization history for persons for whom consent to participate in the registry has been obtained.

(d) A parent may provide evidence of a child's immunization history, in a format provided by the department or one substantially similar, directly to the department for inclusion in the registry. The department shall ensure that the immunization history submitted by a parent is medically verified immunization information by requiring the parent to submit evidence that includes a copy of one or more of the following:

(1) the child's medical record indicating the immunization history and including a provider's signature and the name and address of the provider;

(2) A vaccine-specific invoice from a health care provider for the immunization;

(3) vaccine-specific documentation showing that a claim for the immunization was paid by a payor;

(4) an immunization record signed by a school official; or

(5) an immunization history provided by a local or state immunization registry.

(e) The department shall provide notice to a provider that submits an immunization history for a person for whom consent cannot be verified. The notice shall contain instructions for obtaining consent and resubmitting the immunization history to the department.

(f) A provider shall, upon request of the department, provide additional information to clarify an immunization history submitted to the department.

(g) The department shall provide instruction and education to providers about the immunization registry provider application and enrollment process and expedite processing of provider applications.

§100.7. Official Immunization Record.

An immunization record obtained from the immunization registry shall be accepted as an official immunization record of the child.

§100.8. Complaints.

(a) A person may file a complaint with the department related to the department's failure to comply with a request for exclusion of an individual from the registry by mailing written notification to: Director, Immunization Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756; or by e-mail to the attention of Director, Immunization Division at feedback.ImmDirector@tdh.state.tx.us. The department shall respond to the written complaint within 30 days of receipt of the complaint.

(b) A person may report an incident of discrimination for requesting exclusion of an individual from the registry, or for using an exemption for a required immunization, by mailing written notification to: Director, Immunization Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756; or by e-mail to the attention of Director, Immunization Division at feedback.ImmDirector@tdh.state.tx.us. The department shall respond to the written notification within 30 days of receipt of the notification.

(c) The department shall report to the Legislative Budget Board, the governor, the lieutenant governor, the speaker of the house of representatives, and appropriate committees of the legislature not later than September 30 of each even-numbered year. The report shall:

(1) include the number of complaints received by the department related to the department's failure to comply with requests for exclusion of individuals from the registry; and

(2) identify all reported incidents of discrimination for requesting exclusion of individuals from the registry or for using an exemption for a required immunization.